

#16/RCE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

TITLE: Endoscope with disposable cartridges for the invagination of endoscopic tube

United States Patent and Trademark Office
Honorable Commissioner for Patents
Box RCE,
Washington, D.C. 20231
United States of America

EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 02/02/2003

Please, find attached the following documents:

- | | |
|---|----------|
| 1. Request for Continued Examination transmittal (Form PTO/SB/30) | 1 sheet |
| 2. Credit Card Payment Form PTO-2038*. Payment for RCE pursuant to 37 CFR § 1.114 | 1 sheet |
| 3. Copy of the substitute specification, claims and drawing of the application 09/509,377 | 6 sheets |
| 4. Copy of the applicant's reply on the Final Office Action of November 20, 2002 | 7 sheets |
| 5. Copy of the Request for replacement of examiner with enclosure | 2 sheets |

* Please, note that the credit card will be valid till 08/2003 and the sufficient sum for payment is there.

Faithfully Yours,

Sergey Matasov, M.D.

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Inventor and applicant of
US Patent Application 09 / 509,377
"Endoscope with disposable
cartridges for the invagination of
endoscopic tube"

Riga, January 21, 2003

In re patent of
Voloshin et al.
Patent No. 6,485,409
Issued: November 26, 2002
For: Propulsion of a probe in the colon using a flexible sleeve

Submission of Prior Art Under 37 CFR 1.501

Hon. Assistant Commissioner,

In compliance with 35 U.S.C. § 301 and 37 CFR 1.501 we draw Your attention on the non-patentability of the patent US 6,485,409. The prior art is the application PCT/LV 98/00006.
In compliance with 35 U.S.C. § 102 (b) applicants were not entitled on the patent US 6,485,409 as more than one year prior to the date of application for patent 09/646,941 there was printed publication WO 99/17655 of application PCT/LV 98/00006.

Claims 4,5,10 of patent US 6,485,409 claim the compact condition of the sleeve (26), which is disposed on the distal end of endoscope. In the application PCT/LV98/00006 the identical condition and position of invaginator (23) is described in the specification on the:

- page 1, lines 12-14, 18-21, 31-35;
- page 3, lines 3-4, 17-19, 27-29;
- page 5, lines 7-9;
- page 7, line 38-40;
- page 9, line 11-13;
- page 10, lines 1-3;

as well as is illustrated on Fig. 1.

The examiner of the application PCT/IL00/00017, later of the application 09/646,941 and simultaneously of the application 09/509,377 was Mr. Leubecker, John P. I kindly ask to draw Your attention on the following facts:

- publication WO 99/17655 was not opposed to the application PCT/IL00/00017,
- publication WO 99/17655 was not opposed to the application 09/646,941,
- filing date of the application 09/509,377 in the USPTO is 28.08.00,
- filing date of the application 09/646,941 in the USPTO is 13.11.00,
- 20.11.02 on the application 09/509,377 was issued final rejection,
- 26.11.02 on the application 09/646,941 was issued patent US 6,485,409.

The issue of patent US 6,485,409 has caused to me the moral and material damage. In this connection I had to ask You to annul claims 4,5,10 of patent US 6,485,409.

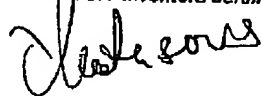
In compliance with 37 CFR 1.501 (c)(2) herewith I sent the letter and its enclosures in duplicate.

Encl.:

- copy of the present letter
- translation of publication WO 99/17655 of the application PCT/LV98/00006 (fragments, mentioned in present letter, are marked)
- certificated copy of the USSR Inventors certificate №1522466 (priority of 21.08.1978) — the prior art of PCT/LV98/00006
- certificated translation of the USSR Inventors certificate №1522466 into English

1 copy 15
2 copies 15
2 copies 15
2 copies 15

Faithfully Yours,
Sergey Matasov M.D.



United States Patent and Trademark Office
Patent Technical Center 3730
Medical Instruments, Diagnostic Equipment,
Treatment Devices, Surgery and Surgical Supplies
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CC: BOX RCE

Riga, February 2, 2003

Re: United States Patent Application 09 / 509,377. Request for replacement of examiner.

Applicant: Dr. Sergey Matasov, inventor
Filing date: 08/28/2000
Title: Endoscope with disposable cartridges for the invagination of endoscopic tube
Art Unit: 3739
Examiner: Leubecker, John P

Dear Director,

Excuse me, please, that I am forced to trouble You in connection with unpleasant matter.
The examiner of the patent application PCT/IL00/00017, then of the patent application 09/646,941 and simultaneously of my application 09/509,377 was one and the same examiner. In this connection it was difficult to me not to draw my attention on the following facts:

1. the publication WO 99/17655 was not opposed to the application PCT/IL00/00017,
2. the publication WO 99/17655 was not opposed to the application 09/646,941,
3. on November 20, 2002 on the application 09/509,377 there was issued the Final Rejection,
4. on November 26, 2002 on the application 09/646,941 there was issued patent US 6,485,409,
5. the claims 4, 5, 10 of US patent 6,485,409 repeats the 1st claim of the application 09/509,377.

I assume that my protest against the claims 4, 5, 10 of the patent US 6,485,409 will seriously embarrass the following examination of my application 09/509,377. In this connection I am forced to ask You for the replacement of examiner.

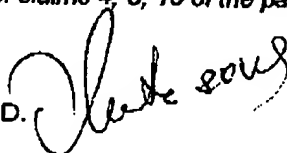
Besides, if You will find it possible, I would be obliged for the abolition of the fee for the continued examination of my application 09/509,377.

Encl.:

Copy of the „Submission of Prior art under 37 CFR 1.501” concerning
the non-patentability of claims 4, 5, 10 of the patent US 6,485,409

1 sheet

Faithfully Yours,
Sergey Matasov, M.D.



BY FAX

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,377	08/28/2000	Sergey Matasov		9553

United States Patent and Trademark Office
 Art Unit 3739
 Examiner Mr. Leubecker, John P.
 Washington, D.C. 20231
 United States of America

EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 02/03/2003

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Please, find attached the reply on the Final Office Action of November 20, 2002 concerning this application (pages 2-7).

Enclosed:

- | | |
|---|----------|
| 1. <i>Amendments.</i> | 3 sheets |
| 2. <i>Remarks/Arguments</i> | 1 sheet |
| 3. <i>Version with markings to show changes made</i> | 4 sheets |
| 4. <i>Substitute specification, claims and drawing of the application 09/509,377:</i> | 6 sheets |
| ▪ <i>amended page 3</i> | |
| ▪ <i>amended page 5</i> | |
| ▪ <i>amended page 8</i> | |
| ▪ <i>amended page 9</i> | |
| ▪ <i>drawing 4/4</i> | |
| 5. <i>Certificated translation of the USSR Inventors Certificate № 1522466 into English</i> | 4 sheets |

Faithfully Yours,

Sergey Matasov, M.D.



According to item 1, 2 a, b, c, d.

Thank You for noticed mistakes. Mistakes are corrected.

According to item 4.

ANALYSIS OF THE OBJECTIONS UNDER 35 U.S.C. §112, 1st paragraph OF CLAIM 2

Subject matter of controversy	Objection of the examiner	Reply on the objection
<ul style="list-style-type: none"> • Description of the embodiment of the "compact hollow cylinder placed with a gap 25 to the endoscopic tube 3, such that the cylinder keeps the gap 25 under the action of working pressure" 	<ul style="list-style-type: none"> • "subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that ..." 	<ul style="list-style-type: none"> • The specialists of the enterprise, occupied with the molding of plastic goods, have embodied the subject matter on the basis of the given description: "A compact hollow cylinder of the invaginator can be formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an everisible thin-walled tube placed at any angles with the longitudinal axis of an endoscopic tube" (page 3, paragraph 2 of the application 09/509,377). The corresponding die mold includes the die in the shape of rod and the cylindrical mould. For putting of cartridge on the tube 3 there is necessary the gap 25. The extent of compression of invaginator's pleats, ensuring the forming of the hollow cylinder was determined in experience. It is obvious, that in order to keep the gap 25 not only at putting of cartridge, but also at the working pressure in the cavity 14 the extent of compression of pleats was greater. Taking into account the objection of examiner: <ul style="list-style-type: none"> ▪ the 2nd paragraph on page 3 could be continued as follow: "There are possible two embodiments of the cylinder. In one embodiment the gap 25 is keeping both at putting of cartridge on the endoscopic tube 3, and at the working pressure in the cavity 14. In other – the gap 25 is necessary only for putting of cartridge." (see amended page 3). ▪ the sentence on the page 5, line 3 could be accomplished by phrase "... at that the gap 25 is keeping also at working pressure in the cavity 14" (see amended page 5).
<ul style="list-style-type: none"> • Claim 2. 	<ul style="list-style-type: none"> • "Claim 2 recites that working pressure maintains gap 25. The specification fails to disclose this". 	<ul style="list-style-type: none"> • Here examiner demonstrates the incorrect understanding of claim 2 of application 09/509,377. In fact in claim 2 there was said: "...cylinder keeps the gap 25 under the action of working pressure". Therefore there is no need to make add-ins in the specification. • In item 8 (page 5, lines 1-4 of Office communication), when opposing the US Patent 5,259,364, there is demonstrated the correct understanding of claim 2 of application 09/509,377: "pleats (52) form a compact hollow cylinder which defines a gap (note space between pleats (52) and endoscopic tube (2) in Figure 2), that is maintained under working pressure".

According to item 6.

The claims are amended in compliance with 35 USC § 112:

- the indefinite status of the subject matter of invention is removed,
- the term "the opposing spring" in the amended claims is absent,
- the suggestions regarding the articles "a", "the", the phrase "for example" are realized,
- the term "the body" in the amended claims is absent,
- the term "transformers of pressure" in the amended claims is absent.

According to item 7.

Please, note that 35 USC § 102 was infringed during the examination of US Patent 6,485,409. Its claims 4, 5, 10 include the invaginator, gathered on the distal end of endoscopic device. More than one year prior to the date of the patent application 09/646,941 in the United States, there was publication WO 99/17655, which includes the endoscope with the same invaginator (see page 1, lines 18-19, 23-26, 36-40; page 3, lines 3-5, 17-18, 23-26, 31-35; page 5, lines 7-9; page 7, line 38-40; page 9, line 11-13; page 10, lines 1-3; Fig. 1c, 1e, 1f). Please, note that in compliance with 35 U.S.C. § 102 the application 09/509,377 includes the invention according to inventors certificate № 1522466 (the certified translation is enclosed).

Application/Control Number: 09/509,377
 Art Unit: 3739

Page 3

According to item 8.

ANALYSIS OF THE OBJECTIONS UNDER TO 35 U.S.C. 102 (b) OF CLAIM 1

Subject matter of controversy	Objection of the examiner	Reply on the objection
<p>Novelty* of invaginator 23, which is gathered on the distal part of endoscopic tube 3.</p>	<ul style="list-style-type: none"> • "Claims 1-3 are rejected under 35 U.S.C.102(b) as being anticipated by Bou et al. (US Patent 5,259,364)". • "As shown by Figure 2, the invaginator (24) would be gathered on the distal end (as the endoscopic tube enters anus (30) by pleats (52)(col.5, lines 7-9)". 	<p>The examiner's objection that „the invaginator (24) would be gathered on the distal end..." does not correspond to the:</p> <ul style="list-style-type: none"> ▪ specification, ▪ Figures 1, 2, ▪ physical abilities <p>of the device according to US Patent 5,259,364:</p> <ul style="list-style-type: none"> • «on Figure 2» there is no the version of the examiner, there is no even the distal end of endoscopic tube 2, defined by the head piece 38; • «in col. 5, lines 7-9» there is no the version of the examiner; • in column 5, lines 4-7 there is said: "The inner portion 32 of the eversion tube 24, which extends outwardly from the anus 30, merges in pressure chamber 50 with a supply or storage portion 52 of the eversion tube 24"; • on Fig. 2 the supply or storage portion 52 is illustrated outside the organism, in chamber 50, far from the distal part defined by the head piece 38; • on Fig. 1 there is the lumen between the abutment ring 28 and the stiff sleeve 36. It will never pass the pleats 52 to the distal part of endoscopic tube 2. • on Fig. 2 there is the lumen between the means 70 and the roller pairs 72. It will never pass the pleats 52 to the distal part of endoscopic tube 2. • on Fig. 1 the distal part of tube 2, defined by head piece 38, is enclosed in the one-layer invaginator 32. <p>Thus:</p> <ul style="list-style-type: none"> • in the US Patent 5,259,364, there is no invaginator, initially gathered on the distal part of endoscopic tube; • in the US Patent 5,259,364 there is no invaginator, which "would be gathered on the distal end" of endoscopic tube.**

* Please, note that for the first time the invaginator, gathered on the distal part of endoscopic tube, was described in the USSR Inventors Certificate № 1522466 with priority from 21.08.1978. This invention is indicated in the priority applications, taken as the base of application 09/509,377 (see page 1, lines 1-3 of its specification).

** Please, note that US Patent 5,259,364 was opposed also to the application PCT/IL00/00017. However on it there was issued US Pat 6,485,409 on 26.11.02, wherein claims include the invaginator, gathered on the distal part of endoscope.

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According to item 8.

ANALYSIS OF THE OBJECTIONS UNDER TO 35 U.S.C. 102 (b) OF CLAIM 2

Subject matter of controversy	Objection of the examiner	Reply on the objection
Novelty of invaginator 23, formed in a compact* hollow cylinder, which keeps the gap 25 under the action of working pressure.	<i>„pleats (52) form a compact hollow cylinder which defines a gap (note space between pleats (52) and endoscopic tube (2) in Figure 2), that is maintained under working pressure (col.5, lines 18-22)“.</i>	<p>1. In the US Patent 5,259,364 there is no invaginator in the form of compact hollow cylinder. The examiner's objection that <i>"pleats (52) form a compact hollow cylinder"</i> does not correspond to the:</p> <ul style="list-style-type: none"> ▪ specification, ▪ Fig. 1, 2, ▪ physical abilities <p>of the device according to US Patent 5,259,364:</p> <ul style="list-style-type: none"> • <i>«in col 5, lines 18-22»</i> there is no the version of examiner, • <i>«in Figure 2»</i> under the character (52) there is presented the corrugated tube. The hollow cylinder is presented only by straight lines. • in the specification there is no any idea, that <i>"pleats (52) form a compact hollow cylinder"</i>; • in the specification there is no words <i>„cylinder“</i>, <i>„compact“</i>, word-combinations <i>„compact cylinder“</i>, <i>„compact hollow cylinder“</i> or their synonyms; • in column 5, lines 7-9 there is said, that the portion 52 is disposed <i>„in zig-zag or corrugated manner“</i>; <p>2. In the application 09/509,377 connection between the compact hollow cylinder 23 and its gap 25 has a physical basis. The absence in the US Patent 5,259,364 of compact hollow cylinder of invaginator exempt us from the controversy concerning the presence of a gap in it.</p>

* Please, note that the 35 U.S.C. § 112 demands that the subject matter must be given in exact terms. The compactness of an object is usually evaluated as the mass of the of its volume unit: $\rho = m/V$. However it is complicated to express the compactness of invaginator through „ ρ “. Therefore in the 2nd claim of application 09/509,377 there are given another objective criterions of invaginator's compactness:

- the geometry – the hollow cylinder,
- the gap with the endoscopic tube.

At that one should take into account, that under the atmosphere pressure in cavity 14, the gap 25 is stable, but under the working pressure – is not. For keeping the gap 25 under the working pressure it is necessary to raise the compactness of hollow cylinder of invaginator 23.

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According to item 8.

ANALYSIS OF THE OBJECTIONS UNDER TO 35 U.S.C. 102 (b) OF CLAIM 3

Subject matter of controversy	Objection of the examiner	Reply on the objection
<p>Novelty of the shell 22, enclosing the invaginator.</p>	<p>"pressure chamber (50) meets the limitation of a shell including a gap between and the invaginator (24). The distal end (28) of the shell is joined with an everted end (26) of the invaginator (Fig.2) and the proximal end forms a projection (note horizontally extending back wall 54)".</p>	<ul style="list-style-type: none"> • In the application 09/509,377 there is said: <ul style="list-style-type: none"> • on page 3, 3rd paragraph: "...A disposable sterile cartridge for invagination consists of a shell which has a projection at its proximal end, comprising: an invaginator; a compressed spring..."; • on page 4, line 42-43: "...The distal part of shell 22 is commensurable in relation to length and diameter to uneverted part of invaginator 23..."; • on page 5, line 38-39: "...After the patient has been placed on an endoscopic table a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope"; • In the application 09/509,377 on the Fig. 1b, 1c one can see the cylindrical form of the shell 22. This form is defined by its function as the base of disposable cartridge, as the chamber and the guide of invaginator into the rectum. • In the application 09/509,377 there is used term shell 22, which literally means – the covering, envelope, rind; in technics – the thinwalled layer, enclosing and protecting the object, surrounded by it. • In the US Patent 5,259,364 the detail 28 is called as ambusement ring, the detail 50 – as pressure chamber. • In the US Patent 5,259,364 on the Fig. 2 the details 28 and 50 did not repeat the shape of invaginator. Please, note, that the chamber 50 include the means 70 with roller pairs 72. • The ring 28 and chamber 50 of US Patent 5,259,364 is impossible to insert in the rectum of human. <p>Thus in the US Patent 5,259,364 there is no object, which repeats the form and/or the function of shell 22 from the application 09/509,377. Therefore the US Patent 5,259,364 could not discredit the novelty of application 09/509,377.</p>

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Art Unit: 3739

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According to item 10.

ANALYSIS OF THE OBJECTIONS UNDER TO 35 U.S.C. 103 (a) OF CLAIM 7

Subject matter of controversy	Objection of the examiner	Reply on the objection
<p>The evidence, the state-of-the-art in techniques and novelty of distal drives of traction lines 40, 41, bending the distal end of endoscopic tube 3.</p>	<ul style="list-style-type: none"> • <i>"Bob et al. fails to provide all the particulars of the endoscopic tube (2), and particularly that it includes a bending mechanism with cylinder/piston unit and traction lines".</i> • <i>"Chikama shows that such a bending mechanism is known in an endoscope (note Figures 8 and 21, for example)."</i> • <i>"Since any endoscope could be used in the invention of Bob et al. and endoscopes with particular bending mechanism as claimed are known, it would have been obvious to the skilled artisan to have used any known endoscope, including the one disclosed by Chikama and the Bob et al. invention".</i> 	<ul style="list-style-type: none"> • In the application 09/509,377 in the 7th claim there is told about the transformers of pressure in mechanical movement, which are the distal drives (drive - setting in motion) of traction lines 40, 41, i.e. are approached to the executive mechanism 43. • In the specification on page 3, lines 41-43 there is told, that the drive „creates exertion at the distal end of traction lines" 40, 41. • In the US Patent 4,721,099 the cylinder/piston units are arranged in the handle of endoscope. Therefore they are classified as the proximal drives of traction lines. • In the US Patent 4,721,099 the proximal drives of traction lines solve the ergonomic task. • In the US Patent 4,721,099 there are no distal drives of traction lines. • In the application 09/509,377 the proximal cylinder/piston units 45 are also arranged in the handle 2 of endoscope. They force the pressure in the distal drives of traction lines 40, 41. • In the application 09/509,377 on the Fig. 2 and 3, the distal drives of traction lines 40, 41 are represented in the shape of elongated syphon, which consists of: <ul style="list-style-type: none"> - elastic tube 36, 37; - spring 38, 39; - thread 42; - plug 44. • In the application 09/509,377 the distal drives of traction lines 40, 41 are described on <ul style="list-style-type: none"> • page 3, lines 41-43 - page 4, lines 1-2, • page 6, lines 11-14, • claim 7. • The distal drives could be in the shape of elongated or short syphon or the cylinder/piston unit. <p>Thus, the proximal drives according to the US Patent 4,721,099 does not discredit the novelty of the application 09/509,377.</p>

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Page 7

According to item 11.

ANALYSIS OF THE OBJECTIONS UNDER TO 35 U.S.C. 103 (a) OF CLAIM 8

Subject matter of controversy	Objection of the examiner	Reply on the objection
The evidence, the state-of-the-art in technics and novelty of biopsy forceps 63 in the shape of a flexible tube, which has a piston 66 on the distal end of biopsy channel and the drive of the cutters.	<ul style="list-style-type: none"> • "Bob et al. contemplates use of an endoscope with a forceps tool. However, such generalization fails to provide the particulars of the forceps tool." • "Thus, it would be obvious to one of ordinary skill in the art to use any known forceps when reducing the Bob et al. invention to practice." • Tovey et al. teaches that there is known a forceps tool that comprises a flexible tube (132), a distal piston (156), proximal piston (52) and a traction line (134) (note col.8, lines 17-21 and Figures 2, 5 and 9) 	<ul style="list-style-type: none"> • In the application 09/509,377 on page 5, line 30-31 there is said about "the intensifier of traction line of biopsy forceps 63". But it turned out that it was not enough for understanding. In this connection there is suggested to give the numerical markings to the initially illustrated cutters 70 and their distal intensifier (driver) 71 (see amended pages 4/4 and 8). • <u>About the state of the art in biopsy.</u> In connection with recpeating by the endoscopic tube 3 of all colon curves (see page 2 of application 09/509,377), there appears two problems: <ol style="list-style-type: none"> 1. insertion of forceps 63 into the biopsy channel, 2. coming into operation of the cutters 70. • For solving of the 1st problem the forceps 63 and their channel are mated in the „cylinder-piston” pair. This pair, in addition to forceps 63, made in the shape of two-meter flexible hermetic tube, includes: <ul style="list-style-type: none"> ▪ the piston 66 of biopsy channel, disposed on the distal end of forceps 63, ▪ the seal 64 of the forceps 63, disposed on the entry 67 into biopsy channel, ▪ the source of pressure and vacuum, which is connected through cock 68 to the cavity of biopsy channel. • For solving of the 2nd problem the forceps 63 has the distal drive 71 of cutters 70, which could be used with or without proximal (manual) drive. The distal drive 71 of cutters 70 could be in the shape of „cylinder-piston” unit or syphon, which through the cavity of forceps 63 is connected with the source 69 of pressure and vacuum. • US Patent 5,643,294 does not have any relation to hydraulics, but its details 132, 156, 52, and 134 does not form the distal drive, facilitating the insertion of biopsy forceps or movement of cutters: <ul style="list-style-type: none"> ▪ The detail 132 is the short segment of flexible tube, arranged on the distal end of short surgical instrument (see Fig. 8). Manual insertion of instrument into biopsy channel of laparoscope does not present any difficulties. There is no the seal of biopsy channel (the analogue of the piston 66 in the application 09/509,377) on the end of detail 132. ▪ The piston member 156 is not the piston in a well-known meaning. The piston serves for transforming the mechanical operation into the energy of liquid (gas) pressure and vice versa. There is no piston or others details in US Patent 5,643,294, which transfers the energy of liquid or gas pressure in the mechanical work. ▪ The inflexible central rod 52 is continued by traction line 134, which one is «terminated in a piston member 156 which moves reciprocatingly in a longitudinal direction in response to manipulation of pivoting handle 46» (col. 7, lines 59-62). This citation indicates, that in the US Patent 5,643,294 there is used the well-known manual proximal drive of traction line 134. <p>Thus, the novelty of biopsy forceps in the application 09/509,377 is obvious.</p>